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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,513	11/03/2004	Manoj Kumar	RLL-240US	1194

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RANBAXY INC.
600 COLLEGE ROAD EAST
SUITE 2100
PRINCETON, NJ 08540

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,513	KUMAR ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *all*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pravastatin delivery system for oral administration, does not reasonably provide enablement for the release profiles recite in claim 22. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: breadth of the claims, nature of the invention, state of the prior art, amount of direction provided by the inventor, the level of predictability in the art, the existence of working examples, quantity of experimentation needed to make or use the invention based on the content of the disclosure, and relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors being discussed below:

Breadth of the claims: is broad, independent claim 22 recites a drug delivery system that requires a specific release profile, however, claim 22 does not specifically recite a dosage form with any structure that prompt the release profile.

Amount of direction provided by the inventor: with respect to the guidance, the present specification discloses at least two delivery system, one comprises a core, a subcoating, and an enteric coating; the other requires a core, a subcoating, an enteric coating, an immediate release layer and another enteric coating over the immediate release layer. The specification discloses quite a large group of polymers for the subcoating, and a number of enteric coating polymers. The specification, however, does not teach how to precisely achieve the claimed release profiles given any controlled release dosage forms, using any type of polymers, and any type of enteric polymers. This is further impossible in view of the multitudes of types of suitable cellulosic polymers such as water-soluble, water-insoluble, and multitudes types of suitable enteric polymers such as pH dependent and pH independent. The specification does not provide any guidance as to how one can achieve the claimed specific release profile with any type of dosage structures, such as single coating layer, tablet matrix, and so on. Accordingly, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

As such, the practitioner would turn to trial and error experimentation in order to compose a delivery system comprising pravastatin, without guidance from the specification or the prior art.

The quantity of experimentation: there is a substantial gap between a composition comprising the claimed drug in a specific dosage structure that renders the claimed release profiles, and one comprising any and all types of structures. As stated earlier, polymer coatings comprise a huge class of compounds, and not all of them yield

the same results with a given drug. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The relative skill of those in the art: is very high, *e.g.*, Ph.D. or M.D. level technology.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5, 8-10 and 14-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al. WO 01/34123.

Chen teaches a controlled release oral dosage form comprising compressed tablet core of pravastatin coating with a subcoating layer, and an enteric coating layer (page 14, 2nd paragraph; and page 16). The core further comprises other additives, and

up to about 50% water swellable polymer such as cellulosic polymers (page 14, 3rd and 4th paragraphs; and page 15). The subcoating comprises cellulosic polymers and plasticizer (page 17; and examples). The amount of drug is disclosed in the examples.

Claims 1-17 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Butler et al. US 6,967,218.

Butler teaches a controlled release dosage comprising pravastatin core, coated with an enteric coating (column 6, lines 15-24). Core comprises pravastatin, polyvinyl pyrrolidone, crospovidone, and other additives (column 7, lines 20-28; and column 14, lines 53-65). The dosage form further comprises a sealant or barrier coatings applied between the core and the enteric coating layer, and also outside the enteric layer (column 13, lines 44-62; and column 14, lines 53-65). The dosage form provides the claimed release profile (column 17, lines 40-65; and examples).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al. US 6,967,218, in view of Faour et al. US 6,491,949.

Butler is relied upon for the reasons stated above. Butler does not expressly teach the immediate release layer and a second enteric coating.

Faour teaches a multi-layer controlled release delivery system comprising an external coating comprises an active agent for immediate release, in combination with an enteric polymer such as methacrylate-methacrylate acid copolymer (column 9, lines 16-32). Thus, it would have been obvious to one of ordinary skill in the art to modify the controlled release composition of Butler to include the immediate release layer in view of the teaching of Faour to obtain the claimed invention, because Faour teaches a multi-layer delivery device suitable for a wide variety of drugs, because Faour teaches an immediate release outer coat for immediate delivery to the environment of use but with the protection of enteric polymer, because Butler teaches the desirability of obtaining a controlled release formulation with immediate release therapeutic effect, and because Butler teaches a controlled release dosage form with the claimed release profile.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chhabra et al. is cited as of interest for the teaching of multi-layer controlled release of pravastatin.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615